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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

ASHEN, JON BENJAMIN

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 06/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

9/14

Office Action Summary

Application No.

10/057,928

Applicant(s)

SEGEV, DAVID

Examiner

Jon B. Ashen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-102 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-102 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-39 and 89-93 are drawn to polymeric compounds that are polynucleotide or oligonucleotide analogs and pharmaceutical compositions comprising said polymeric compounds, classified in class 536, subclass 23.1.
 - II. Claims 40-58 are drawn to dimeric compounds, classified in class 536, subclass 18.7.
 - III. Claims 59-70 and 94-102 are drawn to monomeric compounds, classified in class 536, subclass 18.7.
 - IV. Claims 71-78 are drawn to a process of preparing a polymeric compound comprising monomers and dimers, classified in class 435, subclass 18.7
 - V. Claim 79 is drawn to a process of preparing a dimeric compound, classified in class 435, subclass 128.

- VI. Claim 80 is drawn to a process of sequence specific hybridization with a polynucleotide or oligonucleotide analog, classified in class 435, subclass 6.
- VII. Claims 82-85 are drawn to a process of modulating gene expression in an organism using a polynucleotide or oligonucleotide analog, classified in class 514, subclass 44.
- VIII. Claim 86 is drawn to a method of treating a condition associated with undesired protein production in an organism using a polynucleotide or oligonucleotide analog, classified in class 514 subclass 44.
- IX. Claim 87 is drawn to a process of degrading DNA or RNA in the cells of an organism using a polynucleotide or oligonucleotide analog, classified in class 514, subclass 44.
- X. Claim 88 is drawn to a method of killing cells or viruses using a polynucleotide or oligonucleotide analog, classified in class 514, subclass 44.

2. The inventions are distinct, each from the other because of the following reasons:

3. Inventions of groups I and groups II-III are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate products (the inventions of groups II and III) are deemed to be useful as starting material for the preparation of polynucleotide analogs that comprise monomers or dimers, but not both (which would be the invention of group I), and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Therefore, the inventions of group I and of groups II-III are distinct. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Inventions of group II and of group III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, the inventions of groups II and III have separate utilities; e.g., the preparation of polymers by the

condensation of either the dimers of the invention of group II or the monomers of the invention of group III, for example. See MPEP § 806.05(d). Therefore, the inventions of groups II and III are distinct.

5. Inventions of group I and of group IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed can be used to make other and materially different products. The invention of group I is a polymeric compound comprising monomers and dimers. The process of preparing a compound that is a polymer of monomers and dimers (the invention of group IV) can be used to make polymers comprising monomers or dimers, but not both, for example. Therefore, the inventions of group I and of group IV are distinct.

6. Inventions of groups I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The invention of group I is a polymeric compound comprising monomers and dimers. The invention of group V is a process for preparing a compound that is a dimer. In the instant case the different inventions are not disclosed as capable of use together and will have different functions. The polymeric compound that is the invention of group

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I will function as a sequence specific hybridization probe. This is a different function than the invention of group V, a process of preparing a compound that is a dimer.

Therefore, the inventions of group I and of group V are unrelated.

7. Inventions of groups I and of groups VI-X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case group I is drawn to a product that can be used in the processes that are the inventions of groups IV-XI. The inventions of groups VI-X are all drawn to materially different processes of using the invention of group I (specifically the compound of claim 1); e.g., processes for sequence specific hybridization (group VI), modulating gene expression (group VII), treating a condition associated with undesired protein production (group VIII), degrading DNA or RNA (group IX), or killing cells or viruses (group X). Therefore, because the product as claimed, the compound that is the invention of group I, can be used in materially different processes of using that product, the inventions of group I and of groups VI -X are distinct.

8. Inventions of groups II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

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different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). Group II is drawn to dimeric compounds. Group IV is drawn to a process of preparing a polymeric compound comprising monomers and dimers. In the instant case the compound that is the invention of group II can be used in a materially different process of using that product; e.g., preparing a polymeric compound containing dimers only. Therefore, the inventions of group II and of group IV are distinct.

9. Inventions of group II and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). Group II is drawn to dimeric compounds. Group V is drawn to a process of preparing a dimeric compound. In the instant case the process as claimed can be used to make another and materially different product; e.g., a polymeric compound containing dimers only. Therefore, the inventions of group II and of group V are distinct.

10. Inventions of groups III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

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process of using that product (MPEP § 806.05(h)). Group III is drawn to monomeric compounds. Group IV is drawn to a process of preparing a polymeric compound comprising monomers and dimers. In the instant case the compound that is the invention of group II can be used in a materially different process of using that product; e.g., preparing a polymeric compound containing monomers only. Therefore, the inventions of group III and of group IV are distinct.

11. Inventions of groups III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). Group III is drawn to monomeric compounds. Group V is drawn to a process of preparing a dimeric compound. In the instant case the product as claimed can be used in a materially different process; e.g., the preparation of polymeric compounds from monomeric subunits. Therefore, the inventions of group III and of group V are distinct.

12. Inventions of groups II-III and groups VI-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the compounds that are the inventions of groups II and III will have different functions than the methods that are the inventions of

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groups VI-X. The inventions of groups II-III are dimeric and monomeric compounds.

The inventions of groups VI-X are all drawn to different processes of using the invention of group I (specifically the compound of claim 1); e.g., processes for sequence specific hybridization (group VI), modulating gene expression (group VII), treating a condition associated with undesired protein production (group VIII), degrading DNA or RNA (group IX), or killing cells or viruses (group X). The inventions of groups II and III function as starting materials for the preparation of polymeric compounds. The inventions of groups VI-X function to identify a particular nucleotide sequence (group VI), modulate gene expression (group VII), treat a condition (group VIII), degrade DNA or RNA (group IX) or kill cells or viruses (group X). Therefore, because the inventions of groups II and III and groups VI-IX are unrelated because they are not disclosed as capable of use together and have different functions.

13. Inventions of group IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Group IV is drawn to a process of preparing a polymeric compound comprising monomers and dimers. Group V is drawn to a process of preparing a dimeric compound. In the instant case the different inventions are not disclosed as capable of use together and have different functions. The function of the invention of group IV is the preparation of a polymeric compound whereas the function of the

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invention of group V is the preparation of a dimeric compound. Therefore, the inventions of group IV and of group V are unrelated.

14. Inventions of groups IV-V and groups VI-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Group IV is drawn to a process of preparing a polymeric compound comprising monomers and dimers. Group V is drawn to a process of preparing a dimeric compound. The inventions of groups VI-X are all drawn to different processes of sequence specific hybridization (group VI), modulating gene expression (group VII), treating a condition associated with undesired protein production (group VIII), degrading DNA or RNA (group IX), or killing cells or viruses (group X). In the instant case the different inventions are not disclosed as capable of use together and will have different functions. The function of the inventions of groups IV-V is to prepare a polymeric or dimeric compound. The inventions of groups VI-X function to identify a particular nucleotide sequence (group VI), modulate gene expression (group VII), treat a condition (group VIII), degrade DNA or RNA (group IX) or kill cells or viruses (group X). Therefore, the inventions of groups IV-V and groups VI-X are unrelated.

15. Inventions of groups VI-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP §

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808.01). In the instant case the different inventions are not disclosed as capable of use together and have different functions. A process of sequence specific hybridization (group VI) will have a different function than a process of modulating gene expression (groups VII), a process for treating a condition associated with undesired protein production (group VIII), a process for degrading DNA or RNA in cells (group IX) or a process for killing cells or viruses (group X) in an organism.

In particular, the function of a process of sequence specific hybridization (groups IV and V) is to specifically identify the presence of a particular sequence of nucleotides, the function of a process for modulating gene expression (groups VI-VIII) is to exert some type of regulatory control (either inhibition or induction) on the transcription of mRNA from a protein-coding gene, the function of a process for treating a condition associated with undesired protein production (group IX) or for killing cells or viruses (group XI) in an organism is to provide a therapeutic effect (group IX) and the function of a process for degrading DNA or RNA in cells is to inhibit heterologous recombination of genomic DNA with viral or environmental DNA or to limit the over-expression of a given mRNA transcript, for example. Therefore, the inventions of groups VI-X are unrelated.

16. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification and would require divergent searches of both structure and literature databases placing an undue administrative burden on the examiner, restriction for examination purposes as indicated is proper.

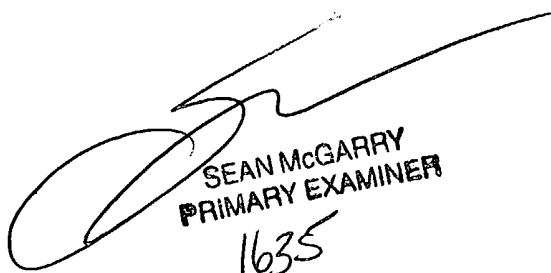
17. A telephone call was made to Anthony Castorina on 6/14/2004 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon B. Ashen whose telephone number is 571-272-2913. The examiner can normally be reached on Monday - Friday, 7:30 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 517-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jba


SEAN MCGARRY
PRIMARY EXAMINER
1635